Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

WHO recommendations on antenatal care for a positive pregnancy experience.

Bibliographic Source(s)

World Health Organization (WHO). WHO recommendations on antenatal care for a positive pregnancy experience. Geneva (Switzerland): World Health Organization (WHO); 2016. 152 p. [214 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
YES	Multidisciplinary Group
YES	Methodologist Involvement
	Patient and Public Perspectives

	Use of a Systematic Review of Evidence
▮▮▮▮▮	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▮	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▯	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▮▮▮▮	External Review
▮▮▮▮▮	Updating

Recommendations

Major Recommendations

Definitions for type of recommendations (Recommended, Context-specific recommendation, Not recommended) are provided at the end of the "Major Recommendations" field.

Refer to the "Remarks" following each recommendation in the original guideline document for additional information.

Nutritional Interventions

Dietary Interventions

Counselling on Healthy Eating and Keeping Physically Active

Counselling about healthy eating and keeping physically active during pregnancy is recommended for pregnant women to stay healthy and to prevent excessive weight gain during pregnancy (Recommended).

Nutrition Education on Energy and Protein Intake

In undernourished populations, nutrition education on increasing daily energy and protein intake is recommended for pregnant women to reduce the risk of low-birth-weight neonates (Context-specific recommendation).

Energy and Protein Dietary Supplements

In undernourished populations, balanced energy and protein dietary supplementation is recommended for pregnant women to reduce the risk of stillbirths and small-for-gestational-age neonates (Context-specific recommendation).

High-protein Supplements

In undernourished populations, high-protein supplementation is not recommended for pregnant women to improve maternal and perinatal outcomes (Not recommended).

Iron and Folic Acid Supplements

Daily Iron and Folic Acid Supplements

Daily oral iron and folic acid supplementation with 30 mg to 60 mg of elemental iron[a] and 400 µg (0.4 mg) folic acid[b] is recommended for pregnant women to prevent maternal anaemia, puerperal sepsis, low birth weight, and preterm birth[c] (Recommended).

[a]The equivalent of 60 mg of elemental iron is 300 mg of ferrous sulfate hepahydrate, 180 mg of ferrous fumarate or 500 mg of ferrous gluconate.
[b]Folic acid should be commenced as early as possible (ideally before conception) to prevent neural tube defects.
[c]This recommendation supersedes the previous WHO recommendation found in the 2012 *Guideline: daily iron and folic acid supplementation in pregnant women*.

Intermittent Iron and Folic Acid Supplements

Intermittent oral iron and folic acid supplementation with 120 mg of elemental iron[a] and 2800 µg (2.8 mg) of folic acid once weekly is recommended for pregnant women to improve maternal and neonatal outcomes if daily iron is not acceptable due to side effects, and in populations with an anaemia prevalence among pregnant women of less than 20% (Context-specific recommendation).

[a]The equivalent of 120 mg of elemental iron is 600 mg of ferrous sulfate hepahydrate, 360 mg of ferrous fumarate or 1000 mg of ferrous gluconate.

Calcium Supplements

In populations with low dietary calcium intake, daily calcium supplementation (1.5–2.0 g oral elemental calcium) is recommended for pregnant women to reduce the risk of pre-eclampsia (Context-specific recommendation).

Vitamin A Supplements

Vitamin A supplementation is only recommended for pregnant women in areas where vitamin A deficiency is a severe public health problem, to prevent night blindness (Context-specific recommendation).

Zinc Supplements

Zinc supplementation for pregnant women is only recommended in the context of rigorous research (Context-specific recommendation – research).

Multiple Micronutrient (MMN) Supplements

Multiple micronutrient supplementation is not recommended for pregnant women to improve maternal and perinatal outcomes (Not recommended).

Vitamin B6 (Pyridoxine) Supplements

Vitamin B6 (pyridoxine) supplementation is not recommended for pregnant women to improve maternal and perinatal outcomes (Not recommended).

Vitamin E and C Supplements

Vitamin E and C supplementation is not recommended for pregnant women to improve maternal and perinatal outcomes (Not recommended).

Vitamin D Supplements

Vitamin D supplementation is not recommended for pregnant women to improve maternal and perinatal

outcomes (Not recommended).

Restricting Caffeine Intake

For pregnant women with high daily caffeine intake (more than 300 mg per day),[a] lowering daily caffeine intake during pregnancy is recommended to reduce the risk of pregnancy loss and low-birth-weight neonates (Context-specific recommendation).

[a]This includes any product, beverage or food containing caffeine (i.e., brewed coffee, tea, cola-type soft drinks, caffeinated energy drinks, chocolate, caffeine tablets).

Maternal and Fetal Assessment

Maternal Assessment

Anaemia

Full blood count testing is the recommended method for diagnosing anaemia during pregnancy. In settings where full blood count testing is not available, on-site haemoglobin testing with a haemoglobinometer is recommended over the use of the haemoglobin colour scale as the method for diagnosing anaemia in pregnancy (Context-specific recommendation).

Asymptomatic Bacteriuria (ASB)

Midstream urine culture is the recommended method for diagnosing asymptomatic bacteriuria (ASB) in pregnancy. In settings where urine culture is not available, on-site midstream urine Gram-staining is recommended over the use of dipstick tests as the method for diagnosing ASB in pregnancy (Context-specific recommendation).

Intimate Partner Violence (IPV)

Clinical enquiry about the possibility of intimate partner violence (IPV) should be strongly considered at antenatal care visits when assessing conditions that may be caused or complicated by IPV in order to improve clinical diagnosis and subsequent care, where there is the capacity to provide a supportive response (including referral where appropriate) and where the WHO minimum requirements are met[a] (Context-specific recommendation).

[a]Minimum requirements are: a protocol/standard operating procedure; training on how to ask about IPV, and on how to provide the minimum response or beyond; private setting; confidentiality ensured; system for referral in place; and time to allow for appropriate disclosure.

Gestational Diabetes Mellitus (GDM)

Hyperglycaemia first detected at any time during pregnancy should be classified as either gestational diabetes mellitus (GDM) or diabetes mellitus in pregnancy, according to WHO criteria[a] (Recommended).

[a]This is not a recommendation on routine screening for hyperglycaemia in pregnancy. It has been adapted and integrated from the 2013 WHO publication *Diagnostic criteria and classification of hyperglycaemia first detected in pregnancy*, which states that GDM should be diagnosed at any time in pregnancy if one or more of the following criteria are met:

Fasting plasma glucose 5.1–6.9 mmol/L (92–125 mg/dL)
1-hour plasma glucose ≥10.0 mmol/L (180 mg/dL) following a 75 g oral glucose load
2-hour plasma glucose 8.5–11.0 mmol/L (153–199 mg/dL) following a 75 g oral glucose load

Diabetes mellitus in pregnancy should be diagnosed if one or more of the following criteria are met:

Fasting plasma glucose ≥7.0 mmol/L (126 mg/dL)
2-hour plasma glucose ≥11.1 mmol/L (200 mg/dL) following a 75 g oral glucose load
Random plasma glucose ≥11.1 mmol/L (200 mg/dL) in the presence of diabetes symptoms

Tobacco Use

Health-care providers should ask all pregnant women about their tobacco use (past and present) and exposure to second-hand smoke as early as possible in pregnancy and at every antenatal care visit (Recommended).

Substance Use

Health-care providers should ask all pregnant women about their use of alcohol and other substances (past and present) as early as possible in the pregnancy and at every antenatal care visit (Recommended).

Human Immunodeficiency Virus (HIV) and Syphilis

In high-prevalence settings,[a] provider-initiated testing and counselling (PITC) for HIV should be considered a routine component of the package of care for pregnant women in all antenatal care settings. In low-prevalence settings, PITC can be considered for pregnant women in antenatal care settings as a key component of the effort to eliminate mother-to-child transmission of HIV, and to integrate HIV testing with syphilis, viral or other key tests, as relevant to the setting, and to strengthen the underlying maternal and child health systems (Recommended).

[a]High-prevalence settings are defined in the 2015 WHO publication *Consolidated guidelines on HIV testing services* as settings with greater than 5% HIV prevalence in the population being tested. Low-prevalence settings are settings with less than 5% HIV prevalence in the population being tested.

Tuberculosis (TB)

In settings where the tuberculosis (TB) prevalence in the general population is 100/100 000 population or higher, systematic screening for active TB should be considered for pregnant women as part of antenatal care (Context-specific recommendation).

Fetal Assessment

Daily Fetal Movement Counting

Daily fetal movement counting, such as with "count-to-ten" kick charts, is only recommended in the context of rigorous research (Context-specific recommendation – research).

Symphysis-fundal Height (SFH) Measurement

Replacing abdominal palpation with symphysis-fundal height (SFH) measurement for the assessment of fetal growth is not recommended to improve perinatal outcomes. A change from what is usually practiced (abdominal palpation or SFH measurement) in a particular setting is not recommended (Context-specific recommendation).

Antenatal Cardiotocography (CTG)

Routine antenatal cardiotocography is not recommended for pregnant women to improve maternal and perinatal outcomes (Not recommended).

Ultrasound Scan

One ultrasound scan before 24 weeks of gestation (early ultrasound) is recommended for pregnant women to estimate gestational age, improve detection of fetal anomalies and multiple pregnancies, reduce induction of labour for post-term pregnancy, and improve a woman's pregnancy experience (Recommended).

Doppler Ultrasound of Fetal Blood Vessels

Routine Doppler ultrasound examination is not recommended for pregnant women to improve maternal and perinatal outcomes (Not recommended).

Preventive Measures

Antibiotics for Asymptomatic Bacteriuria (ASB)

A seven-day antibiotic regimen is recommended for all pregnant women with asymptomatic bacteriuria (ASB) to prevent persistent bacteriuria, preterm birth and low birth weight (Recommended).

Antibiotic Prophylaxis to Prevent Recurrent Urinary Tract Infections (RUTI)

Antibiotic prophylaxis is only recommended to prevent recurrent urinary tract infections in pregnant women in the context of rigorous research (Context-specific recommendation – research).

Antenatal Anti-D Immunoglobulin Prophylaxis

Antenatal prophylaxis with anti-D immunoglobulin in non-sensitized Rh-negative pregnant women at 28 and 34 weeks of gestation to prevent RhD alloimmunization is recommended only in the context of rigorous research (Context-specific recommendation – research).

Preventive Anthelminthic Treatment

In endemic areas,[a] preventive anthelminthic treatment is recommended for pregnant women after the first trimester as part of worm infection reduction programmes (Context-specific recommendation).

[a]Greater than 20% prevalence of infection with any soil-transmitted helminths.

Tetanus Toxoid Vaccination

Tetanus toxoid vaccination is recommended for all pregnant women, depending on previous tetanus vaccination exposure, to prevent neonatal mortality from tetanus (Recommended).

Intermittent Preventive Treatment of Malaria in Pregnancy (IPTp)

In malaria-endemic areas in Africa, intermittent preventive treatment with sulfadoxine-pyrimethamine (IPTp-SP) is recommended for all pregnant women. Dosing should start in the second trimester, and doses should be given at least one month apart, with the objective of ensuring that at least three doses are received[a] (Context-specific recommendation).

[a]Integrated from the WHO publication *Guidelines for the treatment of malaria* (2015), which also states: "WHO recommends that, in areas of moderate-to-high malaria transmission of Africa, IPTp-SP be given to all pregnant women at each scheduled ANC visit, starting as early as possible in the second trimester, provided that the doses of SP are given at least 1 month apart. WHO recommends a package of interventions for preventing malaria during pregnancy, which includes promotion and use of insecticide-treated nets, as well as IPTp-SP." To ensure that pregnant women in endemic areas start IPTp-SP as early as possible in the second trimester, policy-makers should ensure health system contact with women at 13 weeks of gestation.

Pre-exposure Prophylaxis for HIV Prevention

Oral pre-exposure prophylaxis (PrEP) containing tenofovir disoproxil fumarate (TDF) should be offered as an additional prevention choice for pregnant women at substantial risk of HIV infection as part of combination prevention approaches[a] (Context-specific recommendation).

[a]Integrated from the WHO publication *Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV* (2015). Substantial risk of HIV infection is defined by an incidence of HIV infection in the absence of PrEP that is sufficiently high (>3% incidence) to make offering PrEP potentially cost-saving (or cost-effective). Offering PrEP to people at substantial risk of HIV infection maximizes the benefits relative to the risks and costs.

Interventions for Common Physiological Symptoms

Interventions for Nausea and Vomiting

Ginger, chamomile, vitamin B6 and/or acupuncture are recommended for the relief of nausea in early pregnancy, based on a woman's preferences and available options (Recommended).

Interventions for Heartburn

Advice on diet and lifestyle is recommended to prevent and relieve heartburn in pregnancy. Antacid preparations can be offered to women with troublesome symptoms that are not relieved by lifestyle modification (Recommended).

Interventions for Leg Cramps

Magnesium, calcium or non-pharmacological treatment options can be used for the relief of leg cramps in pregnancy, based on a woman's preferences and available options (Recommended).

Interventions for Low Back and Pelvic Pain

Regular exercise throughout pregnancy is recommended to prevent low back and pelvic pain. There are a number of different treatment options that can be used, such as physiotherapy, support belts and acupuncture, based on a woman's preferences and available options (Recommended).

Interventions for Constipation

Wheat bran or other fibre supplements can be used to relieve constipation in pregnancy if the condition fails to respond to dietary modification, based on a woman's preferences and available options (Recommended).

Interventions for Varicose Veins and Oedema

Non-pharmacological options, such as compression stockings, leg elevation and water immersion, can be used for the management of varicose veins and oedema in pregnancy based on a woman's preferences and available options (Recommended).

Health Systems Interventions to Improve the Utilization and Quality of Antenatal Care (ANC)

Women-held Case Notes

It is recommended that each pregnant woman carries her own case notes during pregnancy to improve continuity, quality of care and her pregnancy experience (Recommended).

Midwife-led Continuity of Care (MLCC)

Midwife-led continuity-of-care models, in which a known midwife or small group of known midwives supports a woman throughout the antenatal, intrapartum and postnatal continuum, are recommended for pregnant women in settings with well functioning midwifery programmes (Context-specific recommendation).

Group Antenatal Care

Group antenatal care provided by qualified health-care professionals may be offered as an alternative to individual antenatal care for pregnant women in the context of rigorous research, depending on a woman's preferences and provided that the infrastructure and resources for delivery of group antenatal care are available (Context-specific recommendation – research).

Community-based Interventions to Improve Communication and Support

Facilitated Participatory Learning and Action (PLA) Cycles with Women's Groups

The implementation of community mobilization through facilitated participatory learning and action (PLA) cycles with women's groups is recommended to improve maternal and newborn health, particularly in rural settings with low access to health services.[a] Participatory women's groups represent an opportunity for women to discuss their needs during pregnancy, including barriers to reaching care, and to increase support to pregnant women (Context-specific recommendation).

[a]Part of this recommendation was integrated from *WHO recommendations on community mobilization through facilitated participatory learning and action cycles with women's groups for maternal and newborn health* (2014).

Community Mobilization and Antenatal Home Visits

Packages of interventions that include household and community mobilization and antenatal home visits are recommended to improve antenatal care utilization and perinatal health outcomes, particularly in rural settings with low access to health services (Context-specific recommendation).

Task Shifting Components of Antenatal Care Delivery

Task shifting the promotion of health-related behaviours for maternal and newborn health[a] to a broad range of cadres, including lay health workers, auxiliary nurses, nurses, midwives and doctors is

recommended (Recommended).

Task shifting the distribution of recommended nutritional supplements and intermittent preventive treatment in pregnancy (IPTp) for malaria prevention to a broad range of cadres, including auxiliary nurses, nurses, midwives and doctors is recommended (Recommended).

[a]Including promotion of the following: care-seeking behaviour and ANC utilization; birth preparedness and complication readiness; sleeping under insecticide-treated bednets; skilled care for childbirth; companionship in labour and childbirth; nutritional advice; nutritional supplements; HIV testing during pregnancy; exclusive breastfeeding; postnatal care and family planning; immunization according to national guidelines.

Recruitment and Retention of Staff in Rural and Remote Areas

Policy-makers should consider educational, regulatory, financial, and personal and professional support interventions to recruit and retain qualified health workers in rural and remote areas (Context-specific recommendation).

Antenatal Care Contact Schedules

Antenatal care models with a minimum of eight contacts are recommended to reduce perinatal mortality and improve women's experience of care (Recommended).

Refer to Box 3 in the original guideline document for relevant recommendations from the *2015 WHO recommendations on health promotion interventions for maternal and newborn health*.

Definitions

Three types of draft recommendation were made, namely:

- Recommended
- Context-specific recommendation:
  - Only in the context of rigorous research
  - Only with targeted monitoring and evaluation
  - Only in other specific contexts
- Not recommended

In the absence of evidence of benefits, evidence of potential harm led to a recommendation against the option. Where evidence of potential harm was found for interventions that were also found to have evidence of important benefits, depending on the level of certainty and likely impact of the harm, such evidence of potential harm was more likely to lead to a context-specific recommendation for the intervention (where the context is explicitly stated within the recommendation).

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Pregnancy

Guideline Category

Evaluation

Management

Prevention

Clinical Specialty

Family Practice

Obstetrics and Gynecology

Intended Users

Advanced Practice Nurses

Health Care Providers

Nurses

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

To provide a clear, evidence-based framework for antenatal care (ANC) practices that empowers all pregnant women and adolescent girls to access the type of person-centred care that they want and need, in accordance with a human rights-based approach

Target Population

All pregnant women and adolescent girls receiving antenatal care (ANC) in any health-care facility or community-based setting and their unborn fetuses and newborns

Interventions and Practices Considered

1. Nutritional interventions
    - Counseling about healthy eating and physical activity
    - Nutrition education on increasing daily energy and protein intake, including supplements
    - Daily iron and folic acid supplements
    - Intermittent iron and folic acid supplements in specific populations
    - Calcium supplements
    - Vitamin A supplements
    - Zinc supplements, in the context of rigorous research
    - Restriction of caffeine intake
2. Maternal assessment
    - Full blood count testing for anaemia
    - Midstream urine culture testing for asymptomatic bacteriuria (ASB)
    - Inquiry about intimate partner violence (IPV)
    - Testing for hyperglycaemia
    - Inquiry about tobacco and alcohol use and substance abuse
    - Routine provider-initiated testing and counselling (PITC) for human immunodeficiency virus (HIV) and syphilis

    - Tuberculosis screening
3. Fetal assessment
    - Daily fetal movement counting
    - Symphysis-fundal height (SFH) measurement
    - Ultrasound scan
4. Preventive measures
    - Antibiotics for ASB
    - Antibiotic prophylaxis for recurrent urinary tract infection (RUTI) in context of rigorous research
    - Antenatal anti-D immunoglobulin administration in context of rigorous research
    - Anthelmintic treatment
    - Tetanus toxoid vaccination
    - Malaria prevention: intermittent preventive treatment in pregnancy (IPTp)
    - Pre-exposure prophylaxis for HIV
5. Interventions for common physiological symptoms
    - Ginger, chamomile, vitamin B6, and/or acupuncture for nausea and vomiting
    - Advice on diet and lifestyle or antacids for heartburn
    - Magnesium, calcium, or non-pharmacological treatment for leg cramps
    - Regular exercise for low back and pelvic pain
    - Wheat bran or fibre supplements for constipation
    - Compression stockings, leg elevation, and water immersion for varicose veins and oedema
6. Health systems interventions to improve utilization and quality of antenatal care
    - Woman-held case notes
    - Midwife-led continuity of care
    - Group antenatal care
    - Household and community mobilization
    - Task shifting to other health workers
    - Interventions to recruit and train staff in rural areas
    - Antenatal contact schedules

Note: The following were considered but not recommended: high-protein supplementation in undernourished populations; multiple micronutrient (MMN), vitamin B6 to improve maternal and perinatal outcomes, vitamins E and C, and vitamin D supplements; routine antenatal cardiotocography; routine Doppler ultrasound of fetal blood vessels.

Major Outcomes Considered

- Maternal outcomes
    - Infections
    - Anaemia
    - Pre-eclampsia/eclampsia
    - Gestational diabetes mellitus
    - Mode of delivery
    - Excessive weight gain
    - Intimate partner violence
    - Side-effects
    - Symptomatic relief
    - Maternal mortality
    - Maternal satisfaction and/or women's rating of usefulness of treatment
- Fetal/neonatal outcomes
    - Neonatal infections
    - Small for gestational age
    - Low birth weight
    - Preterm birth
    - Congenital anomalies
    - Macrosomia/large for gestational age
    - Fetal/neonatal mortality

- Sensitivity and specificity of tests
- Health system outcomes
  - Antenatal care (ANC) coverage
  - Facility-based delivery

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Evidence Identification and Retrieval

Evidence to support this guideline was derived from a number of sources by the Technical Working Group (TWG) of methodologists and systematic review teams that worked closely with the Steering Group. Evidence on effectiveness was mostly derived from Cochrane reviews of randomized controlled trials (RCTs). The Steering Group, in collaboration with the Cochrane Pregnancy and Childbirth Group (PCG) and methodologists from Centro Rosarino de Estudios Perinatales (CREP), initially identified all Cochrane systematic reviews and protocols relevant to antenatal care (ANC). The Cochrane PCG Trials Register was searched for new trials and the relevant systematic reviews were updated accordingly. The updating or completion of Cochrane reviews was a collaborative process between authors of the individual reviews, staff of the PCG, and methodologists from CREP.

The World Health Organization (WHO) Steering Group and the methodologists in the TWG determined the suitability of each Cochrane systematic review to provide the evidence base for the key population, intervention, comparator, outcome (PICO) questions. For suitable reviews, CREP methodologists retrieved the evidence relevant to ANC guideline outcomes, which was evaluated according to standard operating procedures approved by the Steering Group.

If a low-quality review or no systematic review was identified on a priority question, a new systematic review was commissioned from external experts. This was the case with all diagnostic test accuracy (DTA) reviews, the qualitative reviews on women's and health-care providers' views on ANC, and the review on factors affecting ANC intervention implementation at country level. In these instances, the external researchers were asked to prepare standard protocols before embarking on the systematic reviews, including clear PICO questions, criteria for identification of studies (including search strategies for different bibliographic databases), methods for assessing risk of bias and the plan for data analysis. The protocols were reviewed and endorsed by the Steering Group and selected content experts among the guideline development group (GDG) members. WHO information retrieval specialists reviewed the search strategies.

In addition to the Cochrane review evidence, for three questions related to health systems (i.e., those on women-held case notes, group ANC, and interventions to communicate with and support pregnant women), indirect evidence was sought, due to a paucity of direct evidence. This work was commissioned from experts at the Norwegian Public Health Institute who conducted a systematic search for indirect evidence on effects of these interventions covering the preceding five years (i.e., from January 2011 to January 2016), but found no additional evidence.

The DTA reviews on haemoglobin and urine tests were commissioned from methodologists from Queen Mary University of London, in the United Kingdom. For these reviews, EMBASE, LILACS, MEDLINE (OVID), SCOPUS and Web of Science were searched from inception to January 2015, and grey literature was sought by searching GreyOpen.

Two qualitative reviews were commissioned from experts from the University of Central Lancashire, United Kingdom:

> To explore the views, attitudes and experiences of pregnant and postnatal women in high-, medium-, and low-income countries in relation to factors that might form barriers to, or facilitators of, their use of routine ANC services.
> To explore the views, attitudes and experiences of health-care providers in high-, medium- and low-income countries in relation to factors that might form barriers to, or facilitators of, their provision of good quality routine ANC services.

Studies published before 2000 were excluded, to ensure that the data reflected the current generation of women who may encounter ANC, and the current generation of ANC providers. This date range was also intended to capture the time period since the 2002 introduction of the WHO focused ANC (FANC) or "basic" ANC model, which includes four goal-orientated ANC visits.

Finally, two researchers from the London School of Hygiene and Tropical Medicine and the Norwegian Public Health Institute undertook a review of case studies reporting the experiences of countries. The review focused on methods of uptake and implementation of the WHO FANC model, problems experienced by service users and other stakeholders, and the broader context. Data were collected from published studies, reports and other policy documents (see the Web supplement [see the "Availability of Companion Documents" field] for the search strategy), and semi-structured interviews with key stakeholders for each country case study, which included Argentina, Kenya, Thailand and the United Republic of Tanzania.

The entire systematic review development process was iterative, with the methodologists in constant communication with the Steering Group to discuss challenges and agree on solutions. The search strategies for evidence identification and retrieval can be found in Web supplement (see the "Availability of Companion Document" field).

ANC-related Recommendations in Other WHO Guidelines

To avoid duplication and ensure harmonization of recommendations across WHO departments and publications, all relevant WHO Guidelines Review Committee (GRC)-approved guidelines were searched and 21 guidelines containing recommendations relevant to ANC were identified (see Annex 2 in the original guideline document). These recommendations were mapped to the priority questions for this new guideline and the Steering Group reached out to the WHO departments and technical units that had issued the relevant guidance to engage and collaborate with them throughout the process of developing this new ANC guideline. Recommendations found in other WHO guidelines that related to health promotion and the identification of risk factors (e.g., smoking, human immunodeficiency virus [HIV]) during ANC were considered to be within the scope of the guideline, whereas recommendations on management and treatment of risk factors, complications and concurrent diseases were deemed to be beyond the scope of the guideline; for these, the guideline user is referred to the relevant separate WHO guidance.

Number of Source Documents

Evidence on the effectiveness of interventions was derived from 47 systematic reviews (41 Cochrane systematic reviews, 2 test accuracy reviews and 4 non-Cochrane reviews of nonrandomized studies) and was summarized in Grading of Recommendations Assessment, Development and Evaluation (GRADE) tables. A scoping review of what women want from antenatal care (ANC) and what outcomes matter to women informed the values domain. Two qualitative systematic reviews on women's and providers' views

and a review of country case studies contributed evidence on the acceptability and feasibility of interventions.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence in Grading of Recommendations Assessment, Development and Evaluation (GRADE)

High: The guideline development group is very confident that the true effect lies close to that of the estimate of the effect.

Moderate: The guideline development group is moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.

Low: Confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the true effect.

Very low: The guideline development group has very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of the effect

Methods Used to Analyze the Evidence

Meta-Analysis

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Assessment of the quality of individual studies included in Cochrane reviews of intervention studies follows specific and explicit methods for assessing the risk of bias using six standard criteria outlined in the *Cochrane handbook for systematic reviews of interventions*. Each included study is assessed and rated by reviewers to be at low, high or unclear risk of bias for sequence generation, allocation concealment, blinding of study personnel and participants, attrition, selective reporting and other sources of bias, such as publication bias. The assessment of these six criteria provides an overall risk of bias that indicates the likely magnitude and direction of the bias and how it is likely to impact the review findings.

Quality Assessment and Grading of the Evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to appraising the quality of quantitative evidence was used for all the critical outcomes identified in the population, intervention, comparator, outcome (PICOs), and a GRADE profile was prepared for each quantitative outcome within each PICO. Accordingly, the quality of evidence for each outcome was rated as "high," "moderate," "low," or "very low" based on a set of criteria. As a baseline, randomized controlled trials (RCTs) provided "high-quality" evidence, while non-randomized trials and observational studies provided "low-quality" evidence. This baseline quality rating was then downgraded based on consideration of risk of bias, inconsistency, imprecision, indirectness and publication bias. For observational studies, other considerations, such as magnitude of effect, could lead to upgrading of the rating if there were no limitations that indicated a need for downgrading. Grading of Cochrane review evidence and diagnostic test accuracy (DTA) evidence was performed by Centro Rosarino de Estudios Perinatales (CREP) and the

methodologists from Queen Mary University of London, respectively, in accordance with standard operating procedures approved by the Steering Group.

Studies identified for the qualitative reviews were subjected to a simple quality appraisal system using a validated instrument that rated studies against 11 criteria, and then allocated a score from A to D, with D indicating the presence of significant flaws that are very likely to affect the credibility, transferability, dependability and/or confirmability of the study. Studies scoring D were excluded on grounds of poor quality.

The findings of the qualitative reviews were appraised for quality using the GRADE-Confidence in the Evidence from Reviews of Qualitative Research (CERQual) tool. The GRADE-CERQual tool, which uses a similar approach conceptually to other GRADE tools, provides a transparent method for assessing and assigning the level of confidence that can be placed in evidence from reviews of qualitative research. The qualitative review team used the GRADE-CERQual tool to assess the confidence in qualitative review findings, which were assigned to evidence domains on values, acceptability and feasibility according to four components: methodological limitations of the individual studies, adequacy of data, coherence and relevance to the review question of the individual studies contributing to a review finding.

Refer to the systematic reviews (see the "Availability of Companion Documents" field) for additional information.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The guideline was developed in accordance with the methods described in the *World Health Organization (WHO) handbook for guideline development*. In summary, the process included: identification of priority questions and outcomes, retrieval of evidence, assessment and synthesis of the evidence, formulation of recommendations, and planning for the implementation, dissemination, impact evaluation and updating of the guideline.

WHO Steering Group

The WHO Steering Group that guided the entire guideline development process comprised WHO staff members from the Department of Reproductive Health and Research (RHR), the Department of Maternal, Newborn, Child and Adolescent Health (MCA), and the Department of Nutrition for Health and Development (NHD) (see Annex 1 in the original guideline document for the list of members). Regional advisors from WHO regions also participated in the guideline development process. The Steering Group drafted the initial scope of the guideline and drafted the key recommendation questions in PICO format (population, intervention, comparator, outcome), identified individuals to be invited to participate as guideline methodologists and as members of the systematic review teams, the Guideline Development Group (GDG) and the External Review Group (ERG), supervised the evidence retrieval and synthesis, organized the Technical Consultations (or GDG meetings), drafted recommendations, and finalized and published the guideline document. Additionally, the Steering Group will oversee dissemination of the guideline.

Guideline Development Group

The Steering Group identified and invited 20 external experts and stakeholders from the six WHO regions to form the GDG, ensuring geographic representation, gender balance, and no important conflicts of interest. The GDG was a diverse group of individuals with expertise in research, guideline development methods, and clinical policy and programmes relating to interventions for antenatal care (ANC) and service delivery, also including a patient/consumer representative. The curriculum vitae of the members were published on the RHR departmental Web site prior to the GDG meetings (which occurred between

October 2015 and March 2016). Subgroups were invited to each of the meetings based on their expertise.

Selected members of the GDG provided input into the drafting of the scope of the guideline, the PICO questions and the prioritization of outcomes, which guided the evidence reviews. The GDG as a whole appraised the evidence used to inform the guideline, advised on the interpretation of this evidence, formulated the final recommendations at face-to-face meetings, and reviewed and approved the final guideline document before its submission to the WHO Guidelines Review Committee (GRC) for approval. A list of the members of the GDG can be found in Annex 1 of the original guideline document.

Technical Working Group

The Technical Working Group (TWG) comprised systematic review teams and guideline methodologists. In relation to quantitative evidence on the effectiveness of different interventions, the Cochrane Pregnancy and Childbirth Group (PCG) provided input on the scoping of the guideline and supervised the updating of all relevant systematic reviews following the standard processes of the Cochrane Collaboration. The WHO Steering Group worked closely with methodologists from the Centro Rosarino de Estudios Perinatales (CREP), in Argentina, to appraise the evidence from systematic reviews using GRADE (Grading of Recommendations Assessment, Development and Evaluation) methodology.

For qualitative data related to women's and healthcare professionals' views on ANC, two qualitative meta-synthesis experts from the University of Central Lancashire, in the United Kingdom of Great Britain and Northern Ireland (United Kingdom), systematically reviewed qualitative studies and synthesized the evidence to inform the GDG's decision-making, in collaboration with the Steering Group and methodologists from the Norwegian Public Health Institute.

In addition, methodologists from Queen Mary University of London, in the United Kingdom, conducted test accuracy reviews of diagnostic tests relevant to the provision of ANC to support this guideline. The Steering Group also worked closely with experts from the Norwegian Public Health Institute, who assisted with methodological issues relating to the GRADE, GRADE-CERQual (Confidence in the Evidence from Reviews of Qualitative Research), and DECIDE (Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence) tools. In addition, the Steering Group consulted two researchers from the London School of Hygiene and Tropical Medicine and the Norwegian Public Health Institute, who reviewed country case studies to investigate implementation issues relating to the WHO focused ANC (FANC) model. Members of the TWG are listed in Annex 1 of the original guideline document.

External Partners and Observers

Representatives of the International Federation of Gynecology and Obstetrics (FIGO), the International Confederation of Midwives (ICM), the United Nations Population Fund (UNFPA), the United States Agency for International Development (USAID) and the United Nations Children's Fund (UNICEF) were invited to the final GDG meeting to serve as observers. All these organizations are potential implementers of the proposed guideline with a history of collaboration with the WHO Departments of RHR and MCA in guideline dissemination and implementation.

Formulation of the Recommendations

The Steering Group supervised and finalized the preparation of evidence summaries and evidence profiles in collaboration with the guideline methodologists, using the Developing & Evaluating Communication strategies to support Informed Decisions & Practice based on Evidence (DECIDE) framework. DECIDE is an evidence-to-decision (EtD) tool that includes explicit and systematic consideration of evidence on interventions in terms of six domains: effects, values, resources, equity, acceptability and feasibility. For each priority question, judgements are made on the impact of the intervention on each of these domains, in order to inform and guide the decision-making process. Using the DECIDE framework, the Steering Group created summary documents for each priority question covering evidence on each of the six domains. See the original guideline document for a description of the domains.

These evidence summaries and draft recommendations, including GRADE tables and other related

documents, were provided to members of the GDG for comments in advance of the series of three Technical Consultations on the ANC guideline. The certainty of the graded evidence on effectiveness was systematically interpreted in the text according to guidance on reporting review evidence from the Cochrane Effective Practice and Organization of Care (EPOC) Group.

The GDG members and other participants were subsequently invited to attend three Technical Consultations (also called GDG meetings) organized at the WHO headquarters in Geneva, Switzerland, the first two in October 2015 and the third in March 2016 (see Annex 1 in the original guideline document for a full list of participants) to review the evidence and formulate recommendations for the ANC guideline. At these meetings, under the leadership of the GDG chair, GDG members reviewed the evidence summaries, the draft recommendations and any comments received through preliminary feedback. The purpose of the meetings was to reach consensus on each judgement and each recommendation, including its direction and context (if any), and to discuss implementation, monitoring and evaluation, and research priorities related to the recommendations.

Decision-making During the GDG Meetings

The GDG meetings were guided by a clear protocol. Each of the three meetings was designed to allow participants to discuss each of the recommendations drafted by the Steering Group. Where necessary, each of these recommendations was revised through a process of group discussion. The final adoption of each recommendation was confirmed by consensus (i.e., full agreement among all GDG members). The GDG also determined the context of recommendations at the meetings by the same process of consensus, based on discussions around the balance of evidence on benefits and disadvantages of the interventions across the domains evaluated. If GDG members had been unable to reach a consensus, the disputed recommendation, or any other decision, would have been put to a vote, by a show of hands.

Document Preparation

Following these three GDG meetings, members of the Steering Group prepared a draft of the full guideline document with revisions to accurately reflect the deliberations and decisions of the GDG participants. This draft guideline was then sent electronically to the GDG participants for further comments before it was sent to the External Review Group (ERG).

Rating Scheme for the Strength of the Recommendations

Three types of draft recommendation were made, namely:

- Recommended
- Context-specific recommendation:
  - Only in the context of rigorous research
  - Only with targeted monitoring and evaluation
  - Only in other specific contexts
- Not recommended

In the absence of evidence of benefits, evidence of potential harm led to a recommendation against the option. Where evidence of potential harm was found for interventions that were also found to have evidence of important benefits, depending on the level of certainty and likely impact of the harm, such evidence of potential harm was more likely to lead to a context-specific recommendation for the intervention (where the context is explicitly stated within the recommendation).

Cost Analysis

The most relevant resources in the context of the implementation of the antenatal care (ANC) interventions in this guideline mainly included costs for providing medicines, supplies, equipment and skilled human resources. A judgement in favour or against the intervention was likely where the resource implications were clearly advantageous or disadvantageous. Cost evaluation relied on reported estimates

obtained during the evidence retrieval process, a 2013 treatment assumption report, the *WHO compendium of innovative health technologies for low-resource settings*, as well as experiences and opinions of the Guideline Development Group (GDG) members. It was recognized that actual costing of interventions is context-specific and not feasible for a global guideline.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Peer Review

The draft guideline was sent electronically to the Guideline Development Group (GDG) participants for further comments before it was sent to the External Review Group (ERG). The Steering Group carefully evaluated the input of the peer reviewers for inclusion in the guideline document and made revisions to the guideline draft as needed. After the GDG meetings and peer review process, further modifications to the guideline by the Steering Group were limited to corrections of factual errors and improvements in language to address any lack of clarity. The revised final version was returned electronically to the GDG for final approval.

External Review Group

The membership of the ERG was geographically and gender-balanced, and there were no important conflicts of interest that prohibited any member from serving (see Annex 1 in the original guideline document for the list of members). There were six members of the ERG, including technical experts and other stakeholders with sufficient interests in the provision of evidence-based antenatal care (ANC). This group peer reviewed the final guideline document to identify any factual errors and comment on the clarity of the language, contextual issues, and implications for implementation. The group ensured that the guideline decision-making processes had considered and incorporated the contextual values and preferences of persons affected by the recommendations, including pregnant women, health-care professionals and policy-makers. It was not within the ERG's remit to change recommendations previously formulated by the GDG.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

Evidence on the effectiveness of interventions was derived from 47 systematic reviews (41 Cochrane systematic reviews, 2 test accuracy reviews and 4 non-Cochrane reviews of nonrandomized studies) and was summarized in Grading of Recommendations Assessment, Development and Evaluation (GRADE) tables. A scoping review of what women want from antenatal care (ANC) and what outcomes matter to women informed the values domain. Two qualitative systematic reviews on women's and providers' views and a review of country case studies contributed evidence on the acceptability and feasibility of interventions.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- It has been established that by implementing timely and appropriate evidence-based practices, antenatal care (ANC) can save lives. Crucially, ANC also provides the opportunity to communicate with and support women, families and communities at a critical time in the course of a woman's life. The process of developing these recommendations on ANC has highlighted the importance of providing effective communication about physiological, biomedical, behavioural and sociocultural issues, and effective support, including social, cultural, emotional and psychological support, to pregnant women in a respectful way. These communication and support functions of ANC are key, not only to saving lives, but to improving lives, health-care utilization and quality of care. Women's positive experiences during ANC and childbirth can create the foundations for healthy motherhood.
- The Guideline Development Group (GDG) noted that the effects of introducing antenatal ultrasound on population health outcomes and health systems in rural, low-resource settings are unproven. However, the introduction of ultrasound to detect pregnancy complications and confirm fetal viability to the woman and her family in these settings could plausibly increase ANC service utilization and reduce morbidity and mortality, when accompanied by appropriate gestational age estimation, diagnosis, referral and management.
- The practice of woman-held case notes may improve the availability of women's medical records and might also be an effective tool to improve health awareness and client–provider communication.
- Effective interventions in disadvantaged populations could help to address health inequalities.
- Providing antiretroviral therapy (ART) to all pregnant and breastfeeding women living with human immunodeficiency virus (HIV) improves individual health outcomes, prevents mother-to-child transmission of HIV, and prevents horizontal transmission of HIV from the mother to an uninfected sexual partner.

Refer to the "Additional considerations," "Maternal outcomes," and "Fetal and neonatal outcomes" sections in the original guideline document for additional information on benefits of specific interventions.

Potential Harms

- Early detection of fetal compromise could lead to timely clinical interventions to reduce poor perinatal outcomes but might lead to maternal anxiety or unnecessary clinical interventions. It is also possible that the period between decreased fetal movements and fetal death might be too short to allow effective action to be taken.
- There is some evidence that women do not understand that ultrasound is a diagnostic tool, and that adverse findings during scans might increase anxiety and distress.
- Moderate-certainty evidence shows that intermittent iron supplementation is probably less commonly associated with nausea than daily iron supplementation (7 trials, 1034 women; RR: 0.60, 95% CI: 0.37–0.97). However, the evidence on other specific side-effects (constipation, diarrhoea, heartburn or vomiting) or any side-effect is of very low certainty.
- Side-effects and safety of pharmacological agents were poorly reported in the included studies. However, drowsiness is a common side-effect of various antihistamines used to treat nausea and vomiting.
- Metoclopramide is generally not recommended in the first trimester of pregnancy, but is widely used. A study of over 81,700 singleton births in Israel reported that they found no statistically significant differences in the risk of major congenital malformations, low birth weight, preterm birth or perinatal death between neonates exposed (3458 neonates) and not exposed to metoclopramide in the first trimester of gestation.
- Women should be informed that it is unclear whether there are side-effects to alternative treatment options for low back and pelvic pain (physiotherapy, support belts and acupuncture) due to a paucity of data.
- Side-effects of fibre supplements include abdominal discomfort and diarrhoea.
- A high level of accuracy in detecting asymptomatic bacteriuria (ASB) is important to avoid treating

women unnecessarily, particularly in view of increasing antimicrobial resistance. Based on uncertain evidence, and assuming a prevalence of ASB of 9%, there would be 18 and 118 false-positive tests per 1000 women tested with Gram stain and dipstick tests, respectively. This suggests that, in settings where pregnant women are treated for ASB, dipstick diagnosis of ASB might lead to many women receiving unnecessary treatment.
- Apart from false reassurance, which might occur with both symphysis-fundal height (SFH) measurement and clinical palpation, there is no evidence of harm with SFH measurement.

Refer to the "Additional considerations," "Maternal outcomes," and "Fetal and neonatal outcomes" sections in the original guideline document for additional information on harms of specific interventions.

Qualifying Statements

Qualifying Statements

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Implementation of the Guideline

Description of Implementation Strategy

Refer to Chapter 4 in the original guideline document, "Implementation of the ANC guideline and recommendations: introducing the 2016 WHO ANC model."

Implementation Tools

Foreign Language Translations

Quick Reference Guides/Physician Guides

Slide Presentation

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

World Health Organization (WHO). WHO recommendations on antenatal care for a positive pregnancy experience. Geneva (Switzerland): World Health Organization (WHO); 2016. 152 p. [214 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

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Guideline Developer(s)

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Guideline Committee

Guideline Development Group

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Financial Disclosures/Conflicts of Interest

Declaration of Interests (DOI) by External Contributors

In accordance with the World Health Organization (WHO) handbook for guideline development, all Guideline Development Group (GDG) members, External Review Group (ERG) members and other external collaborators were asked to declare in writing any competing interests (whether academic, financial or other) at the time of the invitation to participate in the antenatal care (ANC) guideline development process. The standard WHO form for DOI was completed and signed by each expert and sent electronically to the responsible technical officer. The WHO Steering Group reviewed all the DOI forms before finalizing experts' invitations to participate. All experts were instructed to notify the responsible technical officer of any change in relevant interests during the course of the process, in order to update and review conflicts of interest accordingly. In addition, experts were requested to submit an electronic copy of their curriculum vitae along with the completed DOI form. The responsible technical officer collated and reviewed signed DOI forms and curriculum vitae, in conjunction with the director of the WHO Department of Reproductive Health and Research (RHR) and, with input from the Steering Group, determined whether a conflict of interest existed. Where any conflict of interest was declared, the Steering Group determined whether it was serious enough to affect the individual's ability to make objective judgements about the evidence or recommendations. To ensure consistency, the Steering Group applied the criteria for assessing the severity of a conflict of interest in the *WHO handbook for guideline development*.

All findings from the received DOI statements were managed in accordance with the WHO DOI guidelines on a case-by-case basis. Where a conflict of interest was not considered significant enough to pose any risk to the guideline development process or reduce its credibility, the expert was only required to declare such conflict at the GDG meeting and no further action was taken. Conflicts of interest that warranted action by WHO staff arose where experts had performed primary research or a systematic review related to any guideline recommendations; in such cases, the experts were restricted from participating in discussions and/or formulating any recommendation related to the area of their conflict of interest. At the final GDG meeting, members were required again to state any conflicts of interest openly to the entire group, and were required to submit a signed and updated version of their earlier DOI statements. A summary of the DOI statements and information on how conflicts of interest were managed are included in Annex 3 of the original guideline document.

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the World Health Organization (WHO) Web site .

Availability of Companion Documents

The following are available:

- WHO recommendations on antenatal care for a positive pregnancy experience. Executive summary. Geneva (Switzerland): World Health Organization (WHO); 2016. 10 p. Available in English, Chinese, French, Portuguese, Spanish, Russian, and Arabic from the World Health Organization (WHO) Web site .
- WHO recommendations on antenatal care for a positive pregnancy experience. Summary: highlights and key messages from the World Health Organization's 2016 global recommendations for routine antenatal care. Geneva (Switzerland): World Health Organization (WHO); 2018. 10 p. Available from the WHO Web site .
- WHO recommendations on antenatal care for a positive pregnancy experience. Web annexes. Geneva (Switzerland): World Health Organization (WHO); 2016. 24 p. Available from the WHO Web site .
- WHO recommendations on antenatal care for a positive pregnancy experience: evidence base. Web supplement. Geneva (Switzerland): World Health Organization (WHO); 2016. 120 p. Available from the WHO Web site .
- WHO guideline on antenatal care (2016) overview. Powerpoint presentation. Geneva (Switzerland): World Health Organization (WHO); 2016. 46 p. Available from the WHO Web site .
- WHO handbook for guideline development. 2nd edition. Geneva (Switzerland): World Health Organization (WHO); 2014. 167 p. Available from the WHO Web site .

The systematic reviews informing the nutrition recommendations are available from the WHO Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on February 19, 2018. The guideline developer agreed to not review the content.

This NEATS assessment was completed by ECRI Institute on February 8, 2018. The information was verified by the guideline developer on March 13, 2018.

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